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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,482	04/03/2001	Menashi A. Cohenford	CYM-035US	2116
23639	7590	02/13/2004		
BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO, SUITE 1800 SAN FRANCISCO, CA 94111-4067				
			EXAMINER SIEW, JEFFREY	
			ART UNIT 1637	PAPER NUMBER

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/825,482

**Applicant(s)**

COHENFORD ET AL.

**Examiner**

Jeffrey Siew

**Art Unit**

1637

-- **Th MAILING DATE of this communication app ars on th cov r she t with th correspondenc address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10-November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-46, 48-56 and 59-66, 70-74 is/are rejected.
- 7) ☒ Claim(s) 47, 57, 58 and 67-69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 38-45, 49, 50-56, 59-65, 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinman (US5,849,497 Dec. 15, 1998) and Orum et al in view of Lancaster et al (US5,863,717 Jan. 26, 1999).

The teachings and suggestions of Orum et al and Steinman are described previously in office action filed 8/7/03.

Steinman do not teach HPV.

Lancaster et al teach PCR amplification of HPV( see whole document). They teach low risk strains HPV 6 & 11 and high risk HPV 16 & 18 (see col. 1 line 26 & 27). They teach the association with pathogenesis of cancer (see col. 1 lines 5-10). They teach the target regions E1, E2, L2 and L1 (see Figure 2A).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Lancaster et al's primers to Steinman method of PCR in order to detect different strains of HPV. Lancaster et al teach that HPV infection has high correlation with cervical cancer. It would have been prima facie obvious to combine Steinman method of strain

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differentiation with Lancaster et al's primers in order to detect the high risk strains HPV in patients.

3. Claims 46,48,66,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinman (US5,849,497 Dec. 15, 1998) and Orum et al in view of Mahoney et al (US6,045,993 April 4, 2000)

The teachings and suggestions of Orum et al and Steinman are described previously.

Steinman do not teach SEQ ID NO:10 and 11 or cervical scrapings.

Mahoney et al teach PCR amplification with primers(see whole doc. esp. abstract). They teach primer of SEQ ID NO:1 which matches claimed SEQ ID NO:11. They teach primer SEQ ID NO:2 which matches claimed SEQ ID NO:10. They teach cervical specimens such as swabs and brushings, scrapings (see col.2 line 34).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Mahoney et al's primers to Steinman method of detection in order to amplify HPV in sample. Mahoney teach the successful amplification with SEQ IDNO:1 & 2 (see example 1). It would have been prima facie obvious to apply Mahoney et al's teachings of primers to Steinman in order to successfully amplify HPV for detection.

4. The response filed 11/10/03 has been fully considered and deemed not persuasive. The response states that Steinman et al teach that PNA have some limitations in that they are not easily synthesized and expensive. However Steinman et al explicitly teach numerous advantages

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such as providing a much stable PNA/DNA complex which effectively blocks amplification. The advantages would outweigh the limitations. Moreover they state that Orum et al do not teach HPV subregions. The limitation is supplied by the third reference Lancaster et al.

Next in regards to the 103 rejections, the response states that no particular motivation in making the specific claimed combination is provided – a plurality of primers substantially complementary to regions of both nucleic acid form at least one selected strain of HPV and non selected strain of HPV. They state that Lancaster et al do not teach any selective amplification of the strains. However they teach of strain differentiation particularly over HPV strain 11,16 & 18 (see col.3 lines 13-25). Moreover the basis of 103 rejection is on the combination of the reference. The primary reference teaches the method of differentiating strains by using primers to selected strain and primers to non selected strain and blocker for the non selected strain. Given Lancaster et al's sequence determinations and primer constructs , it would have been prima facie obvious to combine both Steinham et al's method and Orum et al's PNA blocker to Lancaster et al's HPV sequence in order to amplify select strains. The 103 rejections over secondary reference Lancaster et al and similarly Mahoney et al are maintained.

### SUMMARY

5. Claims 47, 57, 58 & 67-69 are objected for depending on rejected claim. Claim 74 is allowable. There is no prior art that teach or suggest the method using LCR or rolling circle replication. There is no prior art that teach or suggest SEQ ID NO:6 or 7. The closest prior art is Bauer et al who teach SEQ ID NO:21 which is 25 base pairs and used in probing HPV but Bauer et al explicitly state longer probes lead to less mismatches and give preferably sizes of 18-20 bases (see col. 9 lines 5-15).

### CONCLUSION

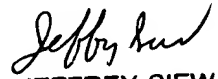
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number before January 22, 2003 is (703) 305-3886 and thereafter can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

  
JEFFREY SIEW  
PRIMARY EXAMINER

February 8, 2004